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PATENT

#22 Brief

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In Re Application of:	Lixiao Wang et al
Application No.:	08/685,338
Filed:	July 23, 1996
For:	HIGH COMPLIANCE, HIGH STRENGTH CATHETER BALLOONS USEFUL FOR TREATMENT OF GASTROINTESTINAL LESIONS
Examiner:	Cris L. Rodriguez
Group Art Unit:	3734

Box AF
Assistant Commissioner for Patents
Washington, D.C. 20231

Docket No.: S63.2-5902

APPEAL BRIEF

This is a Brief on Appeal for the above-identified application in which claims 11-17 and 35-47 were finally rejected in a Final Office Action mailed September 4, 1998. Claims 11-17 and 35-47 are pending. This brief is in furtherance of the Notice of Appeal filed in this case on January 4, 1999. The fees required under §1.17(f) and any required petition for extension of time for filing this brief therefor are dealt with in the accompanying Transmittal Letter. This brief is transmitted in triplicate in accordance with 37 C.F.R. §1.192(a). The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees which may be due with this Appeal.

(1) Real Party in Interest

The application is assigned to SciMed Life Systems, Inc., One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota Corporation and wholly owned subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

(2) Related Appeals and Interferences

At present there are no related appeals or interferences.

(3) Status of Claims

Claims 11-17 and 35-47 have been rejected and are the subject of this appeal.

History Prior to Final Rejection

The instant Application, U.S. Patent Application No. 08/685,338 was filed July 23, 1996. A restriction requirement was issued on September 19, 1997 and responded to on October 17, 1997. A further response to the restriction requirement was made on January 9, 1998, resulting in pending claims 11-17 and 35-47. An official action was issued on February 2, 1998, rejecting 11-17 and 35-47, which was responded to on June 2, 1998, which further was supplemented on August 21, 1998. Claims 11-17 and 35-47 were rejected in a Final Office Action mailed September 4, 1998.

Status After Final Rejection

The Final Rejection was responded to on December 17, 1998. A notice of appeal was filed on January 4, 1999. An Advisory Action was subsequently issued on January 12, stating that, as to pending claims, Applicant' Response to the Final Official Action was not deemed to place the application in condition for allowance.

Claims 11-17 and 35-47 stand rejected and remain pending.

(4) Status of Amendments

No amendments to the claims have been made subsequent to issuance of the Final Office Action.

(5) Summary of the Invention

The presently claimed invention claims a number of balloons, as well as methods

for making said balloons, especially useful for dilatation of gastrointestinal lesions and angioplasty procedures. The balloons have specific minimum burst pressures, a specific minimum diameter at a certain pressure, and a specific average compliance over a certain pressure range, the combinations of which are unprecedented. The favorable combinations of burst strength, compliance and diameter change according to the desired size and compliance of the balloon and are attributable to the inventive method.

Perhaps the most demanding applications for such balloons are in balloon angioplasty in which catheters are inserted for long distances into extremely small vessels and used to open stenoses of blood vessels by balloon inflation. These applications require extremely thin walled, high strength, relatively inelastic balloons of predictable inflation properties. Thin walls are necessary because the balloon's wall and waist thicknesses limit the minimum diameter of the distal end of the catheter and therefore determine the limits on vessel size treatable by the method and the ease of passage of the catheter through the vascular system. High strength is necessary because when the balloon is used to push open a stenosis, the thin wall must not burst under the high internal pressures necessary to accomplish this task. The balloon must have some elasticity so that the inflated diameter can be controlled, enabling the surgeon to vary the balloon's diameter as required to treat individual lesions, but that elasticity must be relatively low so that the diameter is easily controllable. Small variations in pressure must not cause wide variation in diameter. Such angioplasty balloons have nominal diameters in the range of from about 1.25-4.5 mm.

Outside the field of angioplasty, however, relatively high compliant, high strength materials are desirable for some balloons used on esophageal, pyloric, colonic and anastomotic catheters and scopes.

In addition to the above applications, major advances in the ability to access remote areas within the gastrointestinal tract have allowed endoscopists to reach obstructive lesions previously accessible only via open surgical techniques. There are three primary approaches available to the clinician for endoscopic treatment of gastrointestinal strictures: 1) Mercury bougie dilatation; 2) Over-the-wire passage of tapered dilators; and 3) Balloon dilation.

Additional studies have clearly documented the convenience, effectiveness and safety of balloon dilatation of strictures using balloons such as the ones claimed.

There therefore is a need for effective devices which permit endoscopic dilatation of lesions throughout the alimentary tract. It is important that the catheters offer first-use effectiveness in an advanced design to permit rapid inflation, deflation and easy scope passage. The present invention has provided such devices.

During a procedure the balloon is fully inflated to the desired dilatation diameter. Dilatation force is applied for as long as necessary to achieve desired results. Using an inflation apparatus equipped with a pressure gauge, the balloons of the present invention provide a substantially wider range of stricture diameters which may be treated with a single catheter. After treatment, the deflated balloons of the invention provide substantially reduced resistance to withdrawal of the catheter from the body compared to prior art high strength balloons made for instance from biaxially oriented PET. In some TTS applications measured withdrawal force through the scope for catheters bearing balloons of the invention has been found to be only about ½ of the withdrawal force for corresponding catheters bearing PET balloons of similar burst strength.

For esophageal balloon dilatation TTS catheters, a balloon of approximately 8 cm length (dimension B), having an outer diameter (dimension A) of 6 to 20 mm is suitable. The preferred length of the catheter is 180 cm.

For pyloric balloon dilatation TTS catheters, a balloon of approximately 5.5 cm length balloon, having an outer diameter of 6 to 20 mm is suitable. The preferred length of the catheter is 180 cm.

For colonic balloon dilatation TTS catheters, a balloon of approximately 5.5 cm length balloon, having an outer diameter of 6 to 20 mm is suitable. The preferred length of the catheter is 240 cm.

For anastomotic balloon dilatation TTS catheters, a balloon of approximately 8 cm length balloon, having an outer diameter of 20-30 mm is suitable. The preferred length of the catheter is 240 cm.

As further aspects of the invention, there are described herein balloons and methods particularly suited to dilation of GI lesions of various types which are characterized by unique combinations of balloon diameter, high burst strength and high compliance characteristics [claim 46-47 supported at page 6, lines 5-7 and page 8, lines 3-24].

The present invention provides balloons having the desired properties just described. In one aspect, the invention is a method for forming a balloon for a medical device in which a tubing of a thermoplastic polymer material is radially expanded under a first elevated pressure at a first elevated temperature to form the balloon at a first diameter, the thermoplastic polymer material being a block copolymer material [claim 11 and 42 supported at page 8, line 25 to page 9, line 14], and the method including the further step of annealing the balloon at a second elevated temperature less than or equal to the first temperature and a second pressure less than the first elevated pressure for a time sufficient to shrink the formed balloon to a second diameter less than the first diameter [claims 11-17 supported at page 4, lines 12-19, page 12, lines 20-23 and example 2]. Suitably the second temperature is in the range of 70-100°C, the second pressure is no more than about 50 psi, and the time of annealing is sufficient to shrink the balloon so that its diameter at 3 atm pressure is about 90% or less, preferably about 85 % or less, of the 3 atm diameter of a correspondingly prepared balloon prepared without said shrinking step.

In some embodiments to improve balloon-to-balloon reproducibility of the process, the balloon may be shrunk at a very low inflation pressure (typically 0-10 psi) to a nominal diameter below that desired in the final balloon, and then pressurized at a pressure between the shrink pressure and 50 psi, at a temperature within the same range within a mold or cylinder which is sized to provide the desired nominal diameter, still below the diameter at which the balloon was initially blown, and suitably 90% or less of the initial blow diameter.

The shrinking process used in the invention is quite different from the heat set technique used in US 5,500,180, which a main basis for the rejections, in that the process of US 5,500,180, after formation of the balloon heats the balloon under pressure of 100-500 psi to a temperature above the blowing temperature specifically for the purpose of stabilizing and freezing the balloon against shrinkage upon cooling. The present invention is directed to

exploitation of shrinkage behavior in order to increase the compliance of the resulting balloon.

The balloons for the present devices due to the present inventive method have a long dilation length, high operating pressure, typically greater than 50 psi (3 atm, 344.7 kPa) and desirably up to 146 psi, (10 atm, 1013 kPa), low withdrawal force and high compliance. For instance, a compliance change is desirable which would allow a balloon having a 1.25-3.0 mm nominal diameter at 3 atm to grow in a generally linear manner at least 0.25 mm, preferably about 0.5 mm, or more as pressure is increased from 3 to 12 atm. [claims 12-13 supported at page 3, lines 13-14 and examples 3 and 4 and figure 3] With the present method, an even higher burst pressure of up to 20 atm may be obtained within these parameters for theses smaller balloons. Evidence of this may be found in Figure 3 wherein the balloon was shrunk at 95°C for 10 seconds [claim 35].

For balloons about 3.25- 6.0 mm nominal diameter, a growth of at least 1.0 mm over the same range was achieved [claim 14 supported at page 3, lines 15-16 and page 4, lines 11-12]. It has also been found that balloons in this range, 3.0-6.0 mm, can even strengthened enough to have a burst pressure of 20 atm [claim 36 supported at Example 4 and Figure 3]. For balloons in the range of about 6-12 mm nominal diameter, a growth of at least 2.0 mm over a 3-10 atm pressure range was achieved [claims 15 and 37 supported at page 3, lines 16-18, example 5 and Figure 4, 5D]. For even larger diameter balloons, for instance balloons having 3 atm diameters of 12-30 mm, a compliance curve which provides growth of about 3 mm or more, preferably about 4.0 mm or more, over the range of 3 to 9 atm is desirable [claims 16-17 and 38-39 supported at page 3, lines 18-20, example 5 and Figure 4].

The compliance for the balloons by this method can be greatly enhanced as shown above. The Figures, examples and tables pointed out above show comparative studies of what the shrink step accomplishes versus a method which does not utilize the shrink step. The balloons of the various sizes are similarly represented in claims 40-47, in which the compliance is represented as a percentage increase in size over a pressure range. It has been shown that balloons can be made having a burst pressure of at least 9 atm, a diameter at 3 atm of at least 2mm and an average compliance over the range of from 3 atm to burst of at least 3%, even 4 %

per atm [claims 40-41 and 44-45 generally supported at tables 1-2 and Figures 3-5].

As mention above, the thermoplastic polymer material may be a block copolymer, a thermoplastic elastomer, a polymer blend, a random copolymer of rigid and flexible monomers, polyurethanes which have rigid and flexible portions, polyketones, polysulfides or a polyamide homopolymer or copolymer [claim 42 supported at page 8, line 25 to page 9, line 14].

Balloons made of multiple layers of thermoplastic material, such as coextruded balloons or separately blown dual layer balloons may also be employed in the present invention by shrinking the so-formed balloon in accordance with the present invention after it has been formed [claim 43 supported at page 5, lines 6-12 and page 11, line 31 to page 12, line 3].

It has been shown as described above that the balance of high burst strength and high compliance can be achieved at previously unattainable levels utilizing the presently inventive shrink step method. These results have been compared to methods which do not use this step, indicating the effect this shrink step has on the final product. This novel method is applicable to a wide range of sizes of balloons, opening the door to new and improved applications. Such resulting balloon parameters have been previously unattainable.

(6) Issues

I. Whether the Examiner erred in rejecting claim 11 under 35 U.S.C. §102(e) as being anticipated by Anderson et al. (5,500,180).

II. Whether the Examiner erred in rejecting claims 12-17, 35-42, 44 and 45 under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. (5,500,180).

III. Whether the Examiner erred in rejecting claim 43 under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. (5,500,180) in view of Kaneko et al. (5,344,400).

IV. Whether the Examiner erred in rejecting claims 46-47 under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. (5,500,180) in view of Cohen et al. (5,167,239).

(7) Grouping of Claims

For the purposes of this appeal:

For Issue I, claim 11 stands or falls alone;

For Issue II, claims 12-14 stand or fall together; claim 15 stands or falls alone; claims 16-17 stand or fall together; claim 35 stands or falls alone; claim 36 stands or falls alone; claim 37 stands or falls alone; claims 38-39 and 45 stand or fall together; and claims 40-42 and 44 stand or fall together;

For Issue III, claim 43 stands or falls alone; and

For Issue IV, claims 46-47 stand or fall together.

(8) Argument

In the final official action mailed September 4, 1998, claim 11 was rejected under 35 U.S.C. §102(e) and claims 12-17, 35-47 were rejected under 35 U.S.C. §103(a). These rejections are discussed in detail below.

Issue I:

Claim 11 was rejected under 35 U.S.C. §102(e) as being anticipated by Anderson et al. (5,500,180). It is asserted that Anderson et al. discloses a thermoplastic polymer material balloon, where the thermoplastic polymer material is a block copolymer material. The Examiner states in response to Applicant's previous arguments that "product by process claims" are not limited to the manipulation of the recited steps, but only the structure implied by the steps. It is further stated that the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. The Applicant respectfully traverses.

Claim 11 is not anticipated by Anderson et al. not only because Anderson et al. does not teach or suggest a heat shrink step, but because the final products are physically distinct. Evidence of this can be found in the Applicant's specification, for example, in examples 2, 4 and 5 and figures 3-4. These examples show the effect the shrinking step has on the physical properties of the balloons, i.e. their charted physical reaction to pressurization as compared to

balloons that were not subjected to a heat shrinking step. In the second heat step of Anderson et al., instead of reducing the temperature relative to the first heat step, as required by the present invention, it requires that the temperature in the second step be increased. As such, it cannot be presumed, in view of the comparisons shown in the Applicant's specification, that different processes of production applying different parameters would produce balloons that are physically the same. Differences obtained by the process variations within the scope of Applicant's invention, evidenced by the Examples and Figures, are substantial. This contradicts the Examiner's assumption that process is irrelevant in the analysis of claim 11's product-by-process.

Anderson et al. does not disclose or teach each and every element as set forth in claim 11 of the present application. In claim 11, an annealing process which includes heating the balloon material twice at different elevated temperatures and different pressures, wherein the second temperature and pressure are less than the first temperature and pressure. This process results in a shrinking of the balloon's diameter. The balloons prepared utilizing the shrinking step have extended, very high compliance profiles, in addition to high wall strength. The shrinking step causes the compliance curve to start from a lower point so that overall the balloon is much more compliant. The inventive process results in unique combinations of balloon diameter, high burst strength and high compliance characteristics and also provides excellent rewrap characteristics, in comparison to high strength balloons formed by other processes. These are distinct physical characteristics which are displayed by a balloon made by a process utilizing a heat shrinking step, which is not suggested in, and in fact discouraged by, Anderson et al.

Anderson et al. specifically teaches away from the heat shrinking step of the present invention and at the same time claims that the improved properties of its balloon result from the method or process it teaches to form the balloons (see abstract and col 6, lines 13-23 and lines 29-32). It is asserted in Anderson et al. that "[t]he balloons formed using the process...will have an overall advantageous combination of **physical** properties...superior to those exhibited by the "compliant" balloons currently available." The heat set step taught by Anderson et al. clearly is used to contribute to these physical properties.

The heat step is used "to provide the expanded parison and resulting balloon with

thermal and dimensional stability" (col. 7, lines 5-7). "The stability results from the fact that the balloon is heated above the temperature used in the balloon forming process so that the orientation resulting from the processing condition is "locked" into position." (Col. 8, lines 55-60) It is further stated that during the heat step, the parison "is held at a temperature above the temperature at which the balloon was axially stretched and radially expanded, but below the melting temperature of the polymeric material from which the parison was formed."

Once again, "[t]his higher temperature induces crystallization and "freezes" or "locks" the orientation of the polymer chains" (col 9, lines 57-62). The final physical properties of the balloons are dependent upon this heat set step. Lowering the heat set temperature results in balloons exhibiting physical properties which would more likely be adversely affected during a sterilization process (see col. 10, lines 24-27). Balloons created using the heat set step "displayed an improved overall combination of distensibility, elastic stress response and strength when compared to "compliant" balloons of the art" (col 11, lines 48-51). These are all "physical" characteristics which are affected by the heat set step. Example 4 illustrates the importance of the heat set step to the Anderson et al. balloon.

From all of the teachings in Anderson et al., one can logically conclude that a process not using a heat set step would result in a physically and structurally different balloon. Such is the case with a balloon made using the steps of claim 11. Not only does claim 11 not include a heat set step, which crystallizes the balloon, making is less compliant and more rigid, claim 11 directs one to go in the opposite direction by requiring in the second step that the balloon be heated to a temperature **less** than the first elevated temperature, thus "heat shrinking" the balloon. This results in a more compliant balloon and, as mentioned above, a physically different balloon.

In the process of Anderson et al., after formation of the balloon, the balloon is heated under pressure of 100-500 psi to a temperature **above** the blowing temperature specifically for the purpose of stabilizing/crystallizing the balloon **against shrinkage upon cooling**. The present invention is directed to exploitation of shrinkage behavior in order to increase and extend the compliance of the resulting balloon. The entire Anderson et al. patent

teaches the heat step at an increased second temperature, relative to the initial blowing temperature.

Examples of this specific teaching are shown in the patent at Column 9, lines 53-61, Column 10, lines 10-15 and in Example 1. This heat step throughout Anderson et al. teaches in the opposite direction as that of the present application and claim 11 which requires a lower second temperature and pressure relative to the initial blowing temperature and pressure resulting in a structurally different balloon.

The second step of both the presently claimed invention and the Anderson et al. invention is an important step in both inventions in affecting the physical characteristics of the final product. As such, logic dictates that since the second steps of the two teaches are distinctly different, the resulting balloons are distinctly different and therefore claim 11 is clearly distinct and not anticipated by Anderson et al. As agreed, claim 11 requires a step clearly not taught by Anderson et al. and in addition, as discussed above, the final products are structurally different and consequently.

The Examiner cites MPEP 2113, asserting that "product by process claims" are not limited to the manipulation of the recited claims, but only the structure implied by the steps and determination of patentability is based on the product itself. §2113 does state that "if the product in the product-by-process claim is the *same or obvious* from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985) is cited for support. In *In re Thorpe*, the claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate.

The fact that the metal carboxylate is not directly added, but instead produced in-situ does not change the end product. This is not analogous to the present situation. In the cited case, the difference in steps were not indicated to affect the physical characteristics of the final

product, as is the present situation.

In the present situation, the claim calls for treating the materials i.e., the balloon during expansion, differently during the process of making, resulting in, as mentioned above, a balloon having desired physical characteristics. It has been pointed out above that Anderson et al. teaches a divergent heat set treatment step which results in a change of resulting physical characteristics, and that the presently claimed invention calls for a distinct and different shrink step which also affects the physical characteristics of the final balloon. These steps are shown to affect the balloon material in different ways, resulting in physically different final products. This not a mere difference of introducing elements of a compound which react in a mixture to produce the compound rather than just adding the compound itself. In the present situation, the balloon material is treated distinctly differently at a particular step producing a structurally different balloon.

It is well known that one may take two identical polymers and treat them differently, for example heat them differently, and produce two distinct products, even though they still are the same type of product, i.e., balloons, made of the same materials. The balloons may differ in compliance, strength or burst pressure, all of which have been patentably distinct qualities.

As a further example, it is well known that metals, treated in different manner, result in different, patentably distinct products. These situations are more analogous to the present situation. It has been shown above that there is at least one step required in claim 11 that has distinct affects on the balloon material which is polarly distinct from the "corresponding" step of Anderson et al., of which is described to also have a distinct physical effect on the material. As such, it does not logically follow that the two final products are the same or obvious from the prior art, in the context of balloon making, and a *prima facie* is not made to that effect.

Moreover, the obviousness analysis of the Office Action is flawed further in that it fails to take into account the fact that the field of catheter design is a crowded field. Many patents are issued for balloons, and the making thereof, with *seemingly* minor differences in design and physical characteristics because even *seemingly* minor differences in design can yield

products with different physical characteristics.

> "When differences that may appear technologically minor nonetheless have a practical impact, particularly in a crowded field, the decision-maker must consider the obviousness of the new structure in this light." *Continental Can Co. USA Inc. v. Monsanto Co.*, 20 U.S.P.Q. 2d 1746, 1752 (CA FC 1991)

Applicant contends that any obviousness analysis in this case must be made in light of the crowdedness of the field. When the field of balloon making and design as a whole is considered and the range of balloons and their creation considered it will be seen that the particular choices of method and design are *not* the same or obviously similar and hence, is patentable. As such, overruling of the rejection is respectfully requested.

Issue II.

Claims 12-17, 35-42, 44 and 45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. It is asserted that Anderson et al. discloses the invention substantially as claimed, but does not disclose all the different variations of inflation pressure and diameter as claimed. However, it is asserted that, it would be obvious to modify Anderson et al. by providing all the different variations of inflation pressure and diameter to the balloon as an obvious design choice by varying and controlling the specifications in the process of making the balloon. The Applicant respectfully traverses.

Within this Issue, the claims are grouped according to their unique set of parameters. Claims 12-14 are grouped together due to both their dependence upon claim 11, thus having all the elements therein, and their unique set of parameters. These claims target small angioplasty balloons having a high wall strength and a high compliance.

Claim 15 is grouped alone not only for its dependence on claim 11, but because it is targeted to balloons which are larger than the claims 12-14 balloons with a slightly lower burst strength, while maintaining a high compliance.

Claims 16-17 are grouped together not only for its dependence on claim 11, but because it is targeted to balloons which are even distinctly larger than the above angioplasty

balloons with a slightly lower wall strength, while maintaining a high compliance.

These three sets of claims are separated because they target distinctly different types of balloons which are used for different purposes. Specifically they are of different sizes for different applications. Since the size of the balloons affect wall strength and compliance, they should be separated for the appeal. Note that the larger the balloon, the higher the wall strength must be to burst at a given pressure. Thus, the specified burst pressures are quite high for each claim set.

Claim 35 has been grouped alone due to the fact it is not dependent upon claim 11, as claims 12-17, and due to its own unique set of parameters, most notably the high burst pressure of 20 atm. This burst strength is very high for a balloon having the indicated compliance and size. These parameters make the claimed balloon unique.

Claim 36 has been grouped alone also due to the fact it is not dependent upon claim 11, as claims 12-17, and due to its own unique set of parameters, most notably the high burst pressure of 20 atm and the increased size over claim 35. This burst strength is an even more rigorous parameter for a balloon having the indicated compliance and size. These parameters make the claimed balloon even more unique because as the diameter increases wall strength needs to be higher. Thus, 20 atm burst pressure for a 3-6 mm balloon is very remarkable for a balloon having such a compliance.

Claim 37 is grouped alone similarly as claim 15 according to its unique set of parameters focusing on the combination of high compliance and high strength for the particularly indicated growth pattern. These parameters are unique for this size balloon. As mentioned above, the size of the balloons make them distinctly different in that they have differing applications and in that it is unique to have large balloons with high strength and compliance at the same time. It is different from claim 15 in that it is not dependent on claim 11 and therefore does not incorporate the elements of claim 11.

Claims 38-39 and 45 are grouped together because they are targeted toward an even different category of balloons. These balloons are even larger (12mm or more) and have very different uses. Once again, they are distinct for their size and for the unique quality of

maintaining a relatively high wall strength and compliance. As mentioned above, the size of the balloon distinctly affects the other parameters and to balance these parameters in the manner claimed is unique.

Claims 40-42 and 44 are grouped together because they exhibit an even higher distinctive compliance when considering the strength and size of the balloons. This unique compliance is produced by a high shrink rate while having a strong balloon wall.

These groups of claims should be individually evaluated with respect to the prior art because they exhibit separate features of the combination of high compliance and high wall strength for specifically sized balloons, which in fact are not suggested in the prior art or previously attainable.

Claims 12-14:

As to claims 12-14 as discussed above in the response to the §102 rejection, Anderson et al. does not disclose the invention substantially as claimed (claim 11), primarily because of the disparity between the shrinking step of claim 11 and the heating step of Anderson et al. As a result and due to their dependency, claims 12-14 are similarly not made obvious because Anderson et al. does not disclose the invention substantially as claimed, which is an important basis to the rejection in question, and as such the rejection fails. Still further, as discussed above, one skilled in the art would be led in the wrong direction by Anderson et al. in his experimentation of utilizing the two step process to produce a specific compliance. Anderson et al. specifically teaches balloons which are *less compliant* than the present invention and would not fall within the scope of claims 12-14. As mentioned above with regard to Issue I, a *prima facie* case has not been made that the balloons as claimed and the balloons of Anderson et al. are the same or obviously similar, especially in light of the crowdedness of the field. Anderson et al. fails to appreciate the combination of high wall strength and the high compliance over an extended path. Anderson's heat set step may increase wall strength, but it has a detrimental effect on the compliance of the balloon. Thus the combination of parameters specified in claims 12-14 has not been previously attainable. As such, overruling of the rejection is respectfully

requested.

Claim 15:

Claim 15 is also not obvious in view of Anderson et al. for the reasons set out above for claims 12-14. It is further not obvious because the claimed balloons are larger than the above angioplasty balloons, while maintaining a high compliance and relatively high burst strength. As mentioned above, these larger balloons have distinct characteristics and it is increasingly difficult to achieve a relatively high burst strength while maintaining such a high compliance. Anderson does not disclose or suggest achieving such parameters, especially for balloons of such size. Note also that Anderson has no specific teaching regarding balloons for applications which employ 6-12 mm balloons. In fact, Anderson's teachings would make determining these parameters more difficult since the compliance is fixed by the heat set step. As such, overruling of the rejection is respectfully requested.

Claims 16-17:

Claims 16-17 are also not obvious in view of Anderson et al. for the reasons set out above for claims 12-15. It is further not obvious because the claimed balloons are even larger than the above angioplasty balloons (12-30 mm), while maintaining a high compliance and high burst strength. Anderson clearly is not directed toward the making of balloons of this size. The teachings of Anderson would not aid one in achieving the required parameters. In fact, Anderson's teachings would make determining these parameters more difficult since the compliance is fixed by the heat set step. As such, overruling of the rejection is respectfully requested.

Claim 35:

Claim 35, which is not dependent on claim 11, is not obvious for the basic and resulting difference between the shrinking step of the present invention and the heating step of Anderson et al. and due to its own resulting unique set of parameters, most notably the high burst

pressure of 20 atm. This burst strength is high for a balloon having the indicated compliance and size. These parameters make the claimed balloon unique. The Examiner cites no teaching or suggestion in Anderson which would define a balloon having the claimed overall compliance and a burst pressure of *20 atm.*

As pointed out above, Anderson et al. teaches a distinctly different balloon forming method which results in a more rigid, less compliant balloon. Even though Anderson's balloons gain strength from the particular heat step, it is not taught or suggested that a burst pressure of 20 atm, can be obtained together with the required compliance parameters of the subject claim. Therefore, it would not be obvious from the teachings of Anderson et al. to create a balloon which is both compliant and strong enough to fall within the scope of said claim.

The balloons prepared utilizing the shrinking step have extended and very high compliance profiles, in addition to high wall strength. The heat step of Anderson et al. crystallizes or freezes the balloon, making the balloon material more rigid and less compliant. As mentioned above, the shrinking step of the present application causes the compliance curve to start from a lower point so that overall the balloon is much more compliant. A balloon made using the method and materials of the present invention exhibit certain characteristics due to those materials and shrinking method. These characteristics are exemplified in said claim, by claiming how the balloon performs under certain pressure. These characteristics at each point in time, or pressure, define the extended, high compliance curve, which is the result of the materials used and the shrinking method employed. As discussed above, Anderson et al. teaches a distinctly different method of making balloons than that of the presently claimed invention and discloses distinct reasons for the differences in the methods. The present invention seeks **to shrink** the balloon, for the above-mentioned reasons, while Anderson et al. teaches a heat step to stabilize/crystallize the balloon to **guard against shrinkage upon cooling**.

The characteristics defined in the claim under rejection are a result of the method of the presently claimed invention and are not taught by Anderson et al. They are not disclosed because the resulting balloons made by the method of Anderson et al. have distinct and different characteristics due to the above discussed differences in the methods of making balloons, most

notably the differences between the shrinking step of the present invention and the heat step of Anderson et al. Therefore, it is not suggested or obvious in light of Anderson et al. that the balloon characteristics at certain pressures claimed in the rejected claim, which define the improved compliance curve of balloons made by the method of the presently claimed invention, would be obtained from Anderson et al., or by normal variations thereof.

The method used by Applicants is clearly distinct from the methods of Anderson et al., resulting in balloons having differing characteristics, such that the balloons defined by those resulting characteristics would not be obvious over Anderson et al. There is nothing in the record which would lead one to believe that by merely varying and controlling the specifications in the process of making the Anderson balloon, absent the benefit of Applicant's disclosure, could result in balloons having the claimed burst strength and compliance characteristics. In fact, Anderson et al. teaches away from shrinkage which Applicant uses to increase compliance. Any experimentation within the teachings of Anderson would follow this teaching and thus would not result in a balloon which would not fulfil the requirements of claim 35. Specifically, Anderson et al. directs one to use a heat set step and not a heat shrink step, which, as discussed above, is a distinctly different process resulting in a distinctly different balloon. The teachings in Anderson do not give one the capability of making a balloon having the combination of high strength and high and increased compliance as drawn out in the parameters of the claim. Therefore, Applicant respectfully submits that the rejection has been overcome and requests that the rejection be overruled.

Claim 36:

For the reasons stated above with regard to claim 35, claim 36 is similarly not obvious. It is further distinguished from Anderson in that the size of the balloon and the growth rate are both larger. Therefore the claimed burst strength is even more remarkable for a balloon having the indicated compliance and size. These parameters make the claimed balloon even more unique because as the diameter increases wall strength needs to be higher, typically adversely affecting the compliance. Thus, 20 atm burst pressure for a 3-6 mm balloon with the specified with the specified high growth rate is clearly unique over Anderson balloons. It is

respectfully requested that the rejection be overruled.

Claim 37:

Claim 37, which is also not dependent on claim 11, is also not obvious for the basic and resulting difference between the shrinking step of the present invention and the heating step of Anderson et al., as discussed above with regard to claim 35. These basic reasons laid out above for claim 35 apply here as well. Each of these claims have unique parameters, balancing the size of the balloon with surprising combination of high burst strength and high compliance. This balancing is a direct result of the inventive method, as contrasted with Anderson's method above. It has not been sufficiently shown that Anderson teaches or suggests methods for providing this balance of characteristics. Moreover, nothing in Anderson et al. teaches or suggests a balloon of any type within the specified size range of 6-12 mm. Therefore, Applicant respectfully submits that the rejection has been overcome and requests that the rejection be overruled.

Claims 38-39 and 45:

The balloons of claims 38-39 and 45 are even larger than those of claim 37, but the same reasons for which claim 37 is not obvious in view of Anderson apply here as well. Once again, these balloons are distinct for their size and for the unique quality of maintaining a high burst strength and compliance. The balancing of which can contributed to the inventive method of making as discussed above. Anderson does not teach or suggest to one skilled in the art balloons having such parameters, especially balloons of this size. In fact, the even larger size (12 mm +) of the balloons of claims 38-39 and 45 make the teachings of Anderson et al. correspondingly less pertinent. Therefore, Applicant respectfully submits that the rejection has been overcome and requests that the rejection be overruled.

Claims 40-42 and 44:

Claims 40-42 and 44 exhibit a wider range of sizes, but an even higher distinctive

compliance when considering the strength and size of the balloons. This unique compliance is produced by a high shrink rate while having a strong balloon wall. The same reasons for which claims 37-39 are not obvious in view of Anderson apply here as well. Once again, these balloons are distinct for their size and for the unique quality of maintaining a relatively high wall strength and compliance. The balancing of which can contributed to the inventive method of making as discussed, and differentiated from the methods taught by Anderson, above. In this case, the present method used to produce the claimed balloons is even further departed from the teachings of Anderson. As mentioned above, an even higher shrink rate is used to achieve this novel compliance requirement. This further differentiates the Applicant's shrink step from Anderson's heat set step, as contrasted above, lending even more evidence that the resulting balloons are different Anderson does not teach or suggest to one skilled in the art balloons having such parameters, especially balloons of this compliance. Therefore, Applicant respectfully submits that the rejection has been overcome and requests that the rejection be overruled.

Issue III:

Claim 43 was rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. in view of U.S. Patent No. 5,344,400 to Kaneko et al. It is asserted that Anderson et al. discloses the invention substantially as claimed, but does not disclose the balloon formed from at least two concentric layers of different thermoplastic polymers. However, it is asserted that Kaneko et al. teaches a balloon having the missing limitation, and that it would have been obvious to combine the two reference making claim 43 obvious.

In response, Applicant asserts that Anderson et al. does not disclose the invention substantially as claimed, and therefore the rejection fails. Claim 43 depends upon claim 40 and for the above discussed reasons offered in response to the rejection to claim 40 in *Issue II*, Anderson et al. does not disclose the invention substantially as claimed, and as such the asserted rejection fails and Applicant respectfully requests that the rejection be overruled.

Issue IV:

The Examiner also rejects claims 46 and 47 under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. in view of U.S. Patent No. 5,167,239 to Cohen et al. It is asserted that Anderson et al. discloses the invention substantially as claimed, but does not disclose a method of treating a gastrointestinal lesion having the steps as claimed by Applicant. However, it is asserted that Cohen et al. teaches a device having the missing limitation, and that it would have been obvious to combine the two reference making claims 46 and 47 obvious.

In response, Applicant asserts that Anderson et al. does not disclose the invention substantially as claimed, and therefore the rejection fails. Claims 46 and 47 depend upon claim 40 and for the above discussed reasons offered in response to the rejection to claim 40, Anderson et al. does not disclose the invention substantially as claimed, and as such the asserted rejection fails and Applicant respectfully requests that the rejections be overruled.

Conclusion

The pending claims claim subject matter which is patentably distinct from the cited references, and therefore, Appellant urgently requests the Board to reverse the rejections as to claims 11-17 and 35-47 and allow all of the claims of the present application.

Respectfully submitted,

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9. Claims on Appeal:

11. A balloon for a medical device made by the method of:

forming a balloon for a medical device, wherein a tubing of a thermoplastic polymer material is radially expanded under a first elevated pressure at an elevated temperature to form the balloon at a first diameter, the thermoplastic polymer material being a block copolymer material and the method including the further step of annealing the balloon at a second elevated temperature less than the first elevated temperature and a second pressure less than the first elevated pressure for a time sufficient to shrink the formed balloon to a second diameter less than the first diameter.

12. A balloon as in claim 11 having an operating pressure to which the balloon may be safely inflated without bursting of at least 12 atmospheres, a diameter at 3 atmospheres of from about 1.5 to about 3.0 mm, and a diameter growth of at least 0.25 mm over the range of 3-12 atm.

13. A balloon as in claim 12 wherein said diameter growth is at least 0.5 mm.

14. A balloon as in claim 11 having an operating pressure to which the balloon may be safely inflated without bursting of at least 12 atmospheres, a diameter at 3 atmospheres of from about 3.25 to about 6.0 mm, and a diameter growth of at least 1.0 mm over the range of 3-12 atm.

15. A balloon as in claim 11 having an operating pressure to which the balloon may be safely inflated without bursting of at least 10 atmospheres, a diameter at 3 atmospheres of from about 6 to about 12 mm, and a diameter growth of at least 2 mm over the range of 3-10 atm.

16. A balloon as in claim 11 having an operating pressure to which the balloon may be safely inflated without bursting of at least 9 atmospheres, a diameter at 3 atmospheres of from about 12 to about 30 mm, and a diameter growth of at least 3 mm over the range of 3-9 atm.

17. A balloon as in claim 16 wherein said diameter growth is at least 4 mm.

35. A balloon for a medical device characterized by an operating pressure to which the balloon may be safely inflated without bursting of at least 20 atmospheres, a diameter at 3 atmospheres of from about 1.5 to about 3.0 mm, and a diameter growth of at least 0.5 mm over the range of 3-12 atm.

36. A balloon for a medical device characterized by an operating pressure to which the balloon may be safely inflated without bursting of at least 20 atmospheres, a diameter at 3

atmospheres of from about 3.0 to about 6.0 mm, and a diameter growth of at least 1.0 mm over the range of 3-12 atm.

37. A balloon for a medical device characterized by an operating pressure to which the balloon may be safely inflated without bursting of at least 10 atmospheres, a diameter at 3 atmospheres of from about 6 to about 12 mm, and a diameter growth of at least 2 mm over the range of 3-10 atm.

38. A balloon for a medical device characterized by an operating pressure to which the balloon may be safely inflated without bursting of at least 9 atmospheres, a diameter at 3 atmospheres of from about 12 to about 30 mm, and a diameter growth of at least 3 mm over the range of 3-9 atm.

39. A balloon as in claim 38 wherein said diameter growth is at least 4 mm.

40. A balloon for a medical device characterized by a burst pressure of at least 9 atmospheres, a diameter at 3 atmospheres of about 2 mm or more, and an average compliance over the range of from 3 atmospheres to burst of at least 3% per atmosphere.

41. A balloon as in claim 40 wherein said average compliance over the range of from 3 atmospheres to burst is at least 4% per atmosphere.

42. A balloon as in claim 40 made from thermoplastic polymer material which is a block copolymer, a thermoplastic elastomer, a polymer blend, a random copolymer of rigid and flexible monomers, polyurethanes which have rigid and flexible portions, polyketones, polysulfides or a polyamide homopolymer or copolymer.

43. A balloon as in claim 40 formed from at least two concentric layers of different thermoplastic polymers.

44. A balloon as in claim 40 wherein said diameter at 3 atmospheres is about 5 mm or more.

45. A balloon as in claim 40 wherein said diameter at 3 atmospheres is about 12 mm or more.

46. In a method of treating a gastrointestinal lesion by inserting a catheter having a balloon thereon into the gastrointestinal tract, positioning the balloon at the lesion, inflating the balloon to accomplish treatment of the lesion, deflating the balloon and then withdrawing the catheter,

the improvement wherein the balloon is a balloon as in claim 40.

47. A method as in claim 46 wherein the catheter is inserted into the gastrointestinal tract, and withdrawn therefrom, through an endoscope.